The Senate Regulated Industries and Utilities Committee offered the following substitute to HB 614:

A BILL TO BE ENTITLED

AN ACT

To amend Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to controlled substances, so as to enact the "Georgia Prescription Monitoring Program Act"; to provide for legislative intent; to provide for definitions; to provide for the establishment of a program for the monitoring of prescribing and dispensing Schedule II, III, IV, or V controlled substances by the Georgia Drugs and Narcotics Agency; to require dispensers to submit certain information regarding the dispensing of such controlled substances; to provide for the confidentiality of submitted information except under certain circumstances; to authorize the contracting of services relating to the program; to provide for notice and information to prescribers and dispensers; to provide for the establishment of a Prescription Monitoring Program Advisory Committee; to provide for its membership, duties, and organization; to provide for the establishment of rules and regulations; to provide for penalties; to provide for limited liability; to provide for related matters; to provide for an effective date; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to controlled substances, is amended by adding a new article to read as follows:

"ARTICLE 6

16-13-120.

This article shall be known and may be cited as the 'Georgia Prescription Monitoring Program Act.'

16-13-121.

This article is intended to improve health care quality and effectiveness by reducing abuse of controlled substances, reducing duplicative prescribing and overprescribing of controlled substances, and improving controlled substance prescribing practices with the intent of establishing an electronic data base available to dispensers and prescribers of controlled substances.

16-13-122.

As used in this article, the term:

(1) 'Agency' means the Georgia Drugs and Narcotics Agency.

(2) 'Controlled substance' has the same meaning given such term in paragraph (4) of Code Section 16-13-21.

(3) 'Dispenser' means a person that delivers a Schedule II, III, IV, or V controlled substance to the ultimate user but shall not include:

(A) A licensed pharmacy of a hospital that dispenses such substances for the purpose of inpatient or outpatient hospital care, a licensed pharmacy of a hospital or retail pharmacy of a hospital that dispenses prescriptions for controlled substances at the time of dismissal or discharge from such a facility, or a licensed pharmacy of a hospital or retail pharmacy of a hospital that dispenses or administers such substances for long-term care patients or inpatient hospice facilities;

(B) An institutional pharmacy that serves only a health care facility, including, but not limited to, a nursing home, an intermediate care home, a personal care home, or a hospice program, which provides inpatient care and which pharmacy dispenses such substances to be administered and used by a patient on the premises of the facility;

(C) A practitioner or other authorized person who administers such a substance;

(D) A pharmacy operated by, on behalf of, or under contract with the Department of Corrections for the sole and exclusive purpose of providing services in a secure environment to prisoners within a penal institution, penitentiary, prison, detention center, or other secure correctional institution. This shall include correctional institutions operated by private entities in this state which house inmates under the Department of Corrections; or

(E) A licensed veterinarian.

A clinic or other health care facility may apply to the agency for an exemption to be excluded from the definition of this term for purposes of compliance with this article if compliance would impose an undue hardship on such facility. The agency, in consultation with the Composite State Board of Medical Examiners and the Georgia State Board of Pharmacy, shall provide guidelines and criteria for what constitutes an undue

hardship which shall include criteria relating to the amount of indigent patients served and the lack of electronic capability of the facility.

(4) 'Patient' means the person or animal who is the ultimate user of a drug for whom a prescription is issued or for whom a drug is dispensed.

(5) 'Prescriber' means a physician, dentist, optometrist, podiatrist, or other person licensed, registered, or otherwise authorized under the laws of this state to prescribe, distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in this state. This term shall not include a licensed veterinarian.

(6) 'Schedule II, III, IV, or V controlled substance' means a controlled substance that is classified as a Schedule II, III, IV, or V controlled substance under Code Section 16-13-26, 16-13-27, 16-13-28, or 16-13-29, respectively, or under the Federal Controlled Substances Act, 21 U.S.C. Section 812.

16-13-123.

(a) The agency may apply for available grants and accept any gifts, grants, or donations to assist in developing and maintaining the program established by this article.

(b) The agency shall be authorized to grant funds to dispensers for the purpose of covering costs for dedicated equipment and software for dispensers to use in complying with the reporting requirements of this article. Such grants shall be funded by gifts, grants, donations, or other funds appropriated for the operation of the prescription monitoring program established under the provisions of Code Section 16-13-124. The agency shall be authorized to establish standards and specifications for any equipment and software purchased pursuant to a grant received pursuant to this article. Nothing in this article shall be construed to require a dispenser or prescriber to incur costs to purchase equipment and software to comply with this article or to incur ongoing expenses in complying with this article.

16-13-124.

(a) The agency, in consultation with the Composite State Board of Medical Examiners and the Georgia State Board of Pharmacy, shall establish and maintain a program for the monitoring of prescribing and dispensing of all Schedule II, III, IV, or V controlled substances.

(b)(1) Except as otherwise provided for in this Code section, beginning January 1, 2011, each dispenser shall submit to the agency by electronic means information regarding each prescription dispensed for a Schedule II, III, IV, or V controlled substance in accordance with this subsection.

(2) The information submitted for each prescription dispensed for a Schedule II, III, IV, or V controlled substance shall include, but not be limited to:

(A) United States Drug Enforcement Administration (DEA) permit number or approved dispenser facility identification number;

(B) Date prescription filled;

(C) Prescription number;

(D) Whether prescription is new or a refill;

(E) National Drug Code (NDC) for drug dispensed;

(F) Quantity and strength dispensed;

(G) Number of days' supply of the drug;

(H) Patient's name;

(I) Patient's address;

(J) Patient's date of birth;

(K) Approved prescriber identification number;

(L) Date prescription issued by prescriber; and

(M) Other data elements consistent with standards established by the American Society for Automation in Pharmacy, if designated by regulations of the agency.

(3) The agency shall not revise the information required to be submitted by dispensers pursuant to paragraph (2) of this subsection more frequently than annually. Any such change to the required information shall neither be effective nor be applicable to dispensers until six months after the adoption of such changes.

(c) Each dispenser shall weekly submit the information required in subsection (b) of this Code section in accordance with transmission methods and requirements established by the agency and shall report, at a minimum, prescriptions dispensed up to the day prior to data submission.

(d) Dispensers who do not have the technical capabilities to comply with this article shall not be required to submit prescription information prior to July 1, 2011.

(e) Beginning July 1, 2011, the agency may issue a waiver to a dispenser that is unable to submit required prescription information by electronic means acceptable to the agency. Such waiver may permit the dispenser to submit required prescription information by paper form or other means, provided that all information required in subsection (b) of this Code section is submitted in this alternative format subject to the frequency requirements of subsection (c) of this Code section. Requests for waivers shall be submitted in writing.

16-13-125.

(a) Required prescription information submitted to the agency shall be confidential and shall not be subject to open records requirements, as contained in Article 4 of Chapter 18 of Title 50, except as provided in subsections (c) and (d) of this Code section.

(b) The agency shall establish and maintain strict procedures to ensure that the privacy and confidentiality of patients and prescribers and patient and prescriber information collected, recorded, transmitted, and maintained pursuant to this article are protected, including verification of the identity of a recipient of information pursuant to this Code section. Such information shall not be disclosed to persons except as otherwise provided in this article and only in a manner which in no way would conflict with the requirements of the federal Health Insurance Portability and Accountability Act of 1996, P.L. 104-191. This may include, but not be limited to, restricting access only to those individuals and entities which clearly demonstrate a need to know such information.

(c) The agency shall review the required prescription information and if there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, the agency shall notify the appropriate law enforcement or professional licensing, certification, or regulatory board or entity and shall provide prescription information to such board or entity which may be necessary for an investigation. In no event shall the agency be authorized to analyze prescription information of any individual patient or physician unless there is reasonable cause to believe that an impropriety may have occurred.

(d) The agency shall be authorized to provide data collected pursuant to this article to the following persons or under the following circumstances:

(1) Persons authorized to prescribe or dispense controlled substances for the purpose of providing medical or pharmaceutical care for their patients;

(2) Upon the request of a person about whom the information requested concerns or upon the request on his or her behalf by his or her attorney;

(3) The Composite State Board of Medical Examiners, Georgia State Board of Pharmacy, or any licensing board whose practitioners have the authority to prescribe or dispense controlled substances but only as to the practitioners of such board;

(4) Local, state, and federal law enforcement, regulatory, or prosecutorial officials engaged in the administration, investigation, or enforcement of the laws governing licit drugs and who are involved in a bona fide, specific drug related investigation involving a designated case;

(5) Upon the lawful order of a court of competent jurisdiction; and

(6) Personnel of the agency for purposes of administration and enforcement of this article, Article 2 of this chapter, the 'Georgia Controlled Substances Act,' or any other applicable state law.

(e) The agency may provide data to public or private entities for statistical, research, or educational purposes after removing information that could be used to identify prescribers or individual patients or persons who received prescriptions from dispensers.

(f) The agency may provide data to a prescription monitoring program of another state if the confidentiality, security, and privacy standards of the requesting state are determined by the agency to be equivalent to those of the agency.

(g) Any person who receives data or reports relating to this article from the agency shall not provide such data or reports to any other person except by order of a court of competent jurisdiction or as otherwise permitted pursuant to this article.

(h) Prescription information submitted pursuant to this article shall be purged from the data base five years after the prescription was dispensed.

(i) Any permissible user identified in this article who directly accesses data electronically shall implement and maintain a comprehensive information security program that contains administrative, technical, and physical safeguards that are appropriate to the user's size and complexity and to the sensitivity of the personal information obtained. The permissible user shall identify reasonably foreseeable internal and external risks to the security, confidentiality, and integrity of personal information that could result in the unauthorized disclosure, misuse, or other compromise of the information and shall assess the sufficiency of any safeguards in place to control the risks.

16-13-126.

The agency shall be authorized to contract with another state agency or with a private vendor, as necessary, to ensure the effective operation of the prescription monitoring program established pursuant to this article. Any contractor shall be bound to comply with the provisions regarding confidentiality of prescription information in Code Section 16-13-125 and shall be subject to the penalties specified in Code Section 16-13-130 for unlawful acts.

16-13-127.

The agency shall provide notice and information to all prescribers and dispensers in this state as to the intent of this article, the program established pursuant to this article, and instructions on how to submit prescription information to the agency via electronic means.

16-13-128.

(a) There is established a Prescription Monitoring Program Advisory Committee for the purposes of consulting with and advising the agency on matters related to the establishment, maintenance, and operation of the prescription monitoring program established pursuant to this article. This shall include, but not be limited to, data collection, regulation of access to data, evaluation of data to identify benefits and outcomes of the program, communication to prescribers and dispensers as to the intent of the program and how to use the data base, and security of data collected.

(b) The advisory committee shall consist of:

(1) A representative from the Composite State Board of Medical Examiners;

(2) A representative from the Georgia State Board of Pharmacy;

(3) A representative from the Georgia Board of Dentistry;

(4) A board certified oncologist appointed by the agency;

(5) A physician certified in pain management appointed by the agency;

(6) A representative from a licensed hospice appointed by the agency;

(7) An addictive disorders specialist appointed by the agency;

(8) A representative from the Division of Public Health of the Department of Human Resources;

(9) A consumer member;

(10) A representative from the State Board of Optometry; and

(11) A board certified physician who is a dispenser.

Each member of the advisory committee shall serve a two-year term and until the appointment and qualification of such member's successor.

(c) The advisory committee shall elect a chairperson and vice chairperson from among its membership to serve a term of one year.

(d) The advisory committee shall meet at the call of the chairperson or upon request by at least three of the members and shall meet at least one time per year. A majority of the committee shall constitute a quorum.

(e) The members shall receive no compensation or reimbursement of expenses from the state for their services as members of the advisory committee.

16-13-129.

The agency shall promulgate rules and regulations setting forth the procedures and methods for implementing this article. Nothing in this article shall be construed to authorize the agency to establish rules or regulations which limit, revise, or expand or purport to limit, revise, or expand any prescription or dispensing authority of any prescriber or dispenser subject to this article.

16-13-130.

(a) A dispenser who willfully and intentionally fails to submit prescription monitoring information to the agency as required by this article or willfully and intentionally submits incorrect prescription information shall be guilty of a misdemeanor and punished by imprisonment for a period not to exceed 12 months or a fine not to exceed $1,000.00, or both.

(b) An individual authorized to have prescription monitoring information pursuant to this article who willfully and intentionally discloses such information in violation of this article shall be guilty of a felony and punished by imprisonment for a period not to exceed ten years or a fine not to exceed $10,000.00, or both.

(c) An individual authorized to have prescription monitoring information pursuant to this article who willfully and intentionally uses such information in a manner or for a purpose in violation of this article shall be guilty of a felony and punished by imprisonment for a period not to exceed ten years or a fine not to exceed $10,000.00, or both.

(d) The penalties provided by this Code section are intended to be cumulative of other penalties which may be applicable and are not intended to repeal such other penalties.

16-13-131.

Nothing in this article shall require a dispenser or prescriber to obtain information about a patient from the prescription monitoring program established pursuant to this article. A dispenser or prescriber shall not have a duty and shall not be held liable for damages to any person in any civil, criminal, or administrative action for injury, death, or loss to person or property on the basis that the dispenser or prescriber did or did not seek or obtain information from the prescription monitoring program. A dispenser or prescriber acting in good faith shall be immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for requesting or receiving information from the prescription monitoring program."

SECTION 2.

This Act shall become effective on July 1, 2009.

SECTION 3.

All laws and parts of laws in conflict with this Act are repealed.